UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

MEIJER, INC. and MEIJER DISTRIBUTION, INC., on behalf of themselves and all others similarly situated Plaintiffs, v. BIOVAIL CORPORATION, BIOVAIL LABORATORIES. INC., BIOVAIL LABORATORIES INTERNATIONAL SRL, and SMITHKLINE BEECHAM CORP. and GLAXOSMITHKLINE, PLC, Defendants.	Civil Action No. **JURY TRIAL DEMANDED** **CLASS ACTION COMPLAINT**

CLASS ACTION COMPLAINT

Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer" or "Plaintiffs") on behalf of themselves and all others similarly situated, for their Complaint against Defendants Biovail Corporation, Biovail Laboratories, Inc., Biovail Laboratories International SRL (collectively "Biovail"), and SmithKline Beecham Corp. and GlaxoSmithKline plc ("GSK") (collectively "Defendants"), allege as follows based on (a) personal knowledge, (b) the investigation of counsel, including review of pleadings and court orders in patent infringement and other litigation concerning the conduct at issue in this action, and (c) information and belief.

I. NATURE OF THE ACTION

1. This is an antitrust action seeking treble damages arising out of Defendants' unlawful exclusion from the market of AB-rated generic versions of Wellbutrin XL, a prescription antidepressant medication. Annual sales of Wellbutrin XL during the relevant period

exceeded $1.8 billion, making it one of the top selling drugs in the country. As alleged below, Defendants engaged in sham litigation and petitioning and entered into anticompetitive agreements to improperly maintain their monopoly profits in the bupropion HCl extended release market to the detriment of Plaintiffs and the Class of direct purchasers of Wellbutrin XL.

2. Generic versions of brand name drugs contain the same active ingredient, and are found by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between brand name drugs and generics is their price. Generics typically cost at least 30 percent less than their brand counterparts when there is a single generic competitor, and as much as 80 percent less when there are multiple generic competitors on the market. As a result, generics constitute both an opportunity for drug purchasers and consumers to obtain enormous savings, and a threat to the monopoly power and profits of the brand name drug facing generic competition. Indeed, generics typically take 90 percent of the sales from the brand name manufacturer within a year of entry.

3. Acutely aware of these economic realities in the pharmaceutical industry, Defendants embarked on a scheme to maintain the monopoly profits generated by their control of the bupropion HCl extended release market and to eliminate the threat of competition from cost-effective generic substitutes.

4. *First*, after four generic pharmaceutical manufacturers, Anchen Pharmaceuticals, Inc. ("Anchen"), Abrika Pharmaceuticals. Inc. ("Abrika"), Impax Laboratories, Inc. ("Impax"), and Watson Pharmaceuticals, Inc. ("Watson"), filed applications for approval to sell generic versions of Wellbutrin XL, Defendants individually or in concert commenced baseless patent infringement actions against them. These actions were objectively baseless because no reasonable litigant could have realistically expected success on the merits. Defendants

commenced the actions solely for the purpose of delaying lower-priced generic bupropion HCl extended release from reaching the market and maintaining their monopoly in this market. But for the commencement of these actions, generic bupropion HCl extended release would have reached the market no later than November 14, 2005.

5. Defendants' infringement actions were rejected by each of the Courts to which they were brought. In the three individual cases in which patent claim construction hearings were held, before three different United States District Court judges, in three separate United States District Courts, the asserted patent claims were construed in a manner that foreshadowed findings of non-infringement.

6. Moreover, in the only action that reached summary judgment (rather than disposition by settlement), the Court entered summary judgment for the generic competitor, ruling that *the proposed generic formulations did not infringe any Wellbutrin XL patent.*

7. *Second,* in anticipation of defeat in their baseless litigation against the generic competitors, on December 20, 2005, defendant Biovail submitted a citizen petition to the Food and Drug Administration ("FDA") seeking an order requiring the generic competitors to perform additional studies beyond those previously submitted to prove bioequivalence. The citizen petition, like the infringement lawsuits, was objectively baseless, and filed for the improper purpose of further delaying market entry of generic substitutes.

8. The filing of the baseless citizen petition further delayed FDA approval of Anchen's ANDA beyond the date of entry of judgment for Anchen in the infringement lawsuit. It was not until December 14, 2005, four months after entry of judgment in the *Anchen* action, that the FDA denied the citizen petition and permitted Anchen's generic product to go to market. In ruling on the citizen petition, the FDA condemned the filing of the citizen petition, stating that

the brand manufacturers did not have "the right to be free of generic competition" once their patents had been held to be unenforceable, and that under these circumstances, "Biovail [should] not be permitted to shield its market share." According to an analysis reported to the FDA by United States Senators Debbie Stabenow (D-Mich.) and Trent Lott (R-Miss.), the delay in approval of generic bupropion HCl extended release that resulted from the filing of the citizen petition cost consumers $37 million per month. Defendants benefitted from these overpayments.

9. *Third,* when their sham litigations and petitioning activities failed, Biovail, recognizing the imminence of generic entry, entered into agreements with the generic manufacturers further delaying generic entry by some generic manufacturers on some dosage strengths, further delaying the benefits of generic competition from reaching bupropion HCl extended release purchasers, and allowing Defendants to further extend their unlawful monopoly.

10. As a result of Defendants' anticompetitive conduct in the bupropion HCl extended release market, purchasers have been denied the benefits of free and unrestrained competition. More specifically, Plaintiffs and the Class have been denied the opportunity to choose between brand name Wellbutrin XL and lower-priced generic versions and have been made to pay supracompetitive prices for bupropion HCl extended release.

II. JURISDICTION AND VENUE

11. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover threefold damages, costs of suit, reasonable attorneys' fees, for the injuries sustained by Plaintiffs and members of the Direct Purchaser Class resulting from Defendants' unlawful foreclosure of the market for Wellbutrin XL and its AB-rated generic equivalents. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

12. Each Defendant transacts business within this District, and each carries out interstate trade and commerce, in substantial part, in this District. Venue, therefore, is appropriate within this District under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c). Venue is also appropriate with respect to Defendants Biovail Corporation, Biovail Laboratories, Inc., and Biovail Laboratories International SRL under 28 U.S.C. §1391(d).

III. PARTIES

13. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. are corporations organized under the laws of the State of Michigan, with their principal place of business located at 2929 Walker Avenue, NW, Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of the Frank W. Kerr Co., which, during the class period, as defined below, purchased Wellbutrin XL directly and was injured as a result of Defendants' misconduct.

14. Biovail Corporation is a corporation headquartered at 7150 Mississauga Road, Mississauga, Ontario, Canada. Biovail Corporation is engaged in the development, manufacture, and sale of pharmaceutical products. Biovail Corporation is the largest pharmaceutical manufacturer in Canada. Biovail Corporation's products were distributed in the United States during the relevant period by its wholly-owned United States subsidiaries, by its specialty pharmaceutical product sales force. and through joint ventures and agreements with United States pharmaceutical manufacturers including GSK, AstraZeneca Pharmaceuticals, Wyeth, Aventis, and others. Biovail Corporation's shares trade on the New York and Toronto Stock Exchanges.

15. Biovail Corporation has at least three wholly-owned United States subsidiaries. Biovail Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 700 Route 202/206, North Bridgewater, NJ 08807. Biovail Pharmaceuticals, Inc. carries out the business of Biovail Corporation in the United States particularly with respect to administrative

matters, product distribution, and regulatory functions. Biovail Technologies Ltd is a Delaware Corporation located at 3701 Concorde Parkway, Chantilly VA 20151. Biovail Technologies Ltd is in the business of manufacturing pharmaceutical preparations and syrups, and medical instruments. Pharma Pass Inc. is a corporation with its principal place of business at 68 Discovery. Irvine CA 92.618. Pharma Pass Inc. is in the business of developing advanced oral controlled release technologies and formulations for pharmaceutical applications.

16. Defendant Biovail Laboratories, Inc. is a corporation organized and existing under the laws of Barbados, with offices at 100 Chelston Park, Bldg. 2, Collymore Rock, St. Michael, Barbados.

17. Defendant Biovail Laboratories International SRL is a corporation organized and existing under the laws of Barbados, with offices at 100 Chelston Park, Bldg. 2, Collymore Rock, St. Michael, Barbados. Biovail Laboratories International SRL holds the intellectual property that underlies Biovail's Corporation's products, and performs all of the activities that are involved with owning the intellectual property portfolio. Biovail Laboratories International SRL develops, manufactures, and sells Biovail Corporation's pharmaceutical products: it licenses its intellectual property; and it performs strategic planning and decision-making. Biovail Laboratories International SRL owns and operates two manufacturing facilities in Puerto Rico. Defendant Biovail Laboratories International SRL is a successor company to Biovail Laboratories, Inc. and is jointly and severally liable for any harm resulting from its misconduct.

18. Defendant SmithKline Beecham Corporation is a Pennsylvania Corporation with its principal offices located at One Franklin Plaza, Philadelphia, Pennsylvania. SmithKline Beecham Corporation also conducts business in the name of GlaxoSmithKline, and is a subsidiary of GlaxoSmithKline plc.

19. Defendants' actions as part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered, or done by Defendants' officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

IV. CO-CONSPIRATORS

20. With respect to all of the conduct complained of below, at all relevant times the GSK defendants acted in concert with the Biovail defendants.

21. Various other persons, firms and corporations not made defendants herein have participated as co-conspirators with the Defendants in the violations alleged herein and have performed acts and made statements in furtherance thereof.

V. INTERSTATE COMMERCE

22. Defendants' efforts to monopolize and restrain competition in the market for Wellbutrin XL and its AB-rated generic equivalents have substantially affected interstate and foreign commerce.

23. At all material times, Defendants manufactured, promoted, distributed. and sold substantial amounts of Wellbutrin XL in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

24. At all material times, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Wellbutrin XL.

25. In furtherance of their efforts to monopolize and restrain competition in the market for Wellbutrin XL and its AB-rated generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially

affected interstate commerce.

VI. MONOPOLY POWER AND MARKET DEFINITION

26. At all relevant times, Defendants had monopoly power over Wellbutrin XL and its generic equivalents, because they had the power to maintain the price of Wellbutrin XL at supracompetitive levels profitably, without losing substantial sales.

27. A small but significant, non-transitory price increase by Defendants of Wellbutrin XL would not have caused a significant loss of sales to other products.

28. Wellbutrin XL does not exhibit significant, positive cross-elasticity of demand, with respect to price, with any product other than AB-rated generic versions of Wellbutrin XL.

29. Because of, among other reasons, its safety and efficacy profile, Wellbutrin XL is differentiated from all products other than AB-rated generic versions of Wellbutrin XL.

30. Defendants needed to control only Wellbutrin XL and its AB-rated generic equivalents, and no other products, in order to maintain the price of Wellbutrin XL profitably at supracompetitive prices. So while the market entry of a competing, AB-rated generic version of Wellbutrin XL rendered Defendants unable to profitably maintain their current prices of Wellbutrin XL without losing substantial sales, the existence of or entry onto the market of no other drug product on the market would render Defendants so unable.

31. Defendants also sold Wellbutrin XL at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

32. Defendants have had, and exercised, the power to exclude competition to Wellbutrin XL.

33. Defendants at all relevant times enjoyed high barriers to entry with respect to Wellbutrin XL.

34. To the extent that defining a relevant product market is necessary in this case, the relevant product market is Wellbutrin XL and its AB-rated generic equivalents.

35. The relevant geographic market is the United States.

36. At all relevant times, Defendants held a 100% share in the relevant product market in the United States.

VII. MARKET EFFECTS

37. The acts and practices of Defendants had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Wellbutrin XL from generic competition. Defendants' actions allowed Defendants to maintain a monopoly and exclude competition in the market for Wellbutrin XL and its AB-rated generic equivalents, to the detriment of Plaintiffs and all other members of the Direct Purchaser Class.

38. Defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Defendants to sell Wellbutrin XL without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Wellbutrin XL much sooner than they actually will be marketed, and, at all events, would have been on the market no later than November 14, 2005.

39. The generic manufacturers seeking to sell generic Wellbutrin XL had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products.

40. Defendants' illegal acts to delay the introduction into the U.S. marketplace of any generic version of Wellbutrin XL caused Plaintiffs and the Class to pay more than they would have paid for extended-release bupropion HCl products, absent Defendants' illegal conduct.

41. Typically, generic versions of brand-name drugs are initially priced significantly

below the corresponding reference listed drug ("RLD") branded counterpart to which they are AB-rated. As a result, upon generic entry, direct purchasers rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand-name drug continues to lose even more market share to the generics. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand-name drug at a reduced price. Consequently, brand-name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

42. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, direct purchasers, such as Plaintiff, would have paid less for extended-release bupropion HCl by (a) substituting purchases of less-expensive AB-rated generic Wellbutrin XL for their purchases of more-expensive branded Wellbutrin XL, (b) receiving discounts on their remaining branded Wellbutrin XL purchases, and (c) purchasing generic Wellbutrin XL at lower prices sooner.

43. Moreover, due to Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Wellbutrin XL.

44. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT

45. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Wellbutrin XL from Defendants. As a result of Defendants' illegal conduct, members

of the Class were compelled to pay, and did pay, artificially inflated prices for their extended-release bupropion HCl requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Wellbutrin XL was artificially inflated by Defendants' illegal conduct and/or (2) class members were deprived of the opportunity to purchase lower-priced generic versions of Wellbutrin XL sooner.

46. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

IX. LEGAL BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand name Drugs

47. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 ("FDCA"), a manufacturer of a new drug must obtain approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

48. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act. Pub. L. No. 98-417, 98 Stat.1585 (1984) ("Hatch-Waxman"). The purpose of Hatch-Waxman was to hasten the delivery of inexpensive generic drugs to the market while respecting the patent rights of brand name drug patent holders.

49. Typically, generic versions of brand name drugs are priced significantly below their brand name counterparts. Because of the price difference and other institutional features of

the pharmaceutical market, in every state pharmacists are permitted (and in some states, required) to automatically substitute the generic product for a brand name product unless the doctor has stated that the prescription for the brand name product must be dispensed as written.

50. As additional generic manufacturers enter the market, prices for generic versions of a drug decrease predictably because of competition among generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generic accelerates. Generic competition enables purchasers to (a) purchase generic versions of the brand name drug at a substantially lower price, and (b) purchase the brand name drug at a reduced net price.

51. Until a generic manufacturer enters the market, there is no bioequivalent generic drug that can substitute for the brand name drug, and therefore the brand name manufacturer can charge supracompetitive prices profitably without material loss to sales volume. Consequently, brand name drug manufacturers have a strong interest in seeking to delay the introduction of generic competition into the market.

52. Hatch-Waxman represents a significant effort by Congress to hasten the delivery of generic drugs to the market. The principal mechanism Congress used was to eliminate the need for generic manufacturers to file a lengthy and costly NDA to obtain FDA approval for generic substitutes. Instead, under Hatch-Waxman, to obtain approval, the generic manufacturer is permitted to file an ANDA that incorporates the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA and then show only that the proposed generic drug is bioequivalent to the brand name drug, *i.e.,* that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug.

53. Once bioequivalence is demonstrated, the FDA assigns an "AB" rating to the

generic drug, permitting it not only to be sold, but also to be substituted (and in some instances, *required* to be substituted), for the brand name drug at the pharmacy counter.

54. To protect brand name manufacturers' ability to enforce their patents against infringement through the ANDA process, Hatch-Waxman also streamlined the patent enforcement process, providing that the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand name drug for up to 30 months if the patent holder initiated a patent infringement lawsuit against the ANDA applicant.

55. When the FDA approves a brand name manufacturer's NDA, Hatch-Waxman allows the brand manufacturer to list in the FDA' s book of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents.

56. The FDA plays only a ministerial role in Orange Book listings. The FDA relies completely on the brand name manufacturer for information concerning the validity of the patents and applicability of the patents to the brand name drug. The FDA does not check the representations supplied by the brand name manufacturer independently for accuracy or trustworthiness.

57. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

58. If a generic manufacturer files Paragraph I or II certifications, the FDA must act on the application within 180 days of receipt. If a generic manufacturer files a Paragraph III certification, the FDA can proceed with the ANDA approval process, with final approval being granted after the expiration of the applicable patents.

59. If a generic manufacturer files a Paragraph IV certification, however, a brand name manufacturer may delay the final FDA approval of the ANDA by suing for patent infringement. Specifically, if the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. During the pendency of the 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would qualify for final approval but for the 30-month stay, but cannot authorize the generic manufacturer to go to market. Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand name drug manufacturer may delay the date of final approval of the generic drug, and the generic drug's entry into the market.

60. Hatch-Waxman relies on the brand name manufacturer to refrain from (a) listing patents that were improperly procured, or invalid, or not applicable to the brand name drug, and

(b) bringing suit without proof that the generic applicant actually infringes a valid, enforceable, and applicable patent held by the brand name manufacturer.

61. Abuse by brand name manufacturers of the Hatch-Waxman patent protections through improper patent listing or commencement of baseless litigation improperly prevents generic competitors from bringing their less expensive bioequivalent substitute products to market. Such conduct violates antitrust law and harms purchasers of pharmaceutical products.

B. The Availability of Citizen Petitions to Challenge FDA Approval of Generic Drugs

62. Section 505(j) of the FDCA creates a mechanism by which a person may file a petition with the FDA requesting, among other things, that the agency take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a citizen petition.

63. Citizen petitions provide an opportunity for individuals to express their genuine concerns about safety, scientific, or legal issues regarding a product anytime before, or after, its market entry.

64. Other than the form of such citizen petition, the regulations place no restrictions on the subject matter of a citizen petition.

65. The FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days of receipt. That response may be to approve the request in whole or in part, or deny the request. The Commissioner also may provide a tentative response with an estimate on a time for a full response.

66. Reviewing and responding to citizen petitions is a resource-intensive and time consuming task because the FDA must research the petition' s subject, examine scientific,

medical, legal and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. These activities strain the FDA's limited resources, and lengthy citizen petitions can delay FDA approval of generic products even if those petitions ultimately are found to lack merit.

67. Abusive and anticompetitive citizen petitions have become an increasingly common problem in the last several years as brand name companies have sought to compensate for dwindling new product pipelines. In some such cases, citizen petitions have been filed with respect to ANDAs that have been pending for a year or more, long after the brand name manufacturer received notice of the ANDA filing, and have had the effect of delaying the approval of the generic product while the FDA evaluates the citizen petition.

68. Delaying generic competition is a lucrative strategy for an incumbent manufacturer. Given the market's preference for generic products over brand names, the cost of filing an improper citizen petition may be trivial compared to the value of securing even a few months delay in a generic rival's entry into the market.

69. FDA officials have acknowledged abuses of the citizen petition process. FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before." *Speech before the Generic Pharmaceutical Association Annual Policy Conference* (September 19, 2005).

70. In July 2006, Gary Buehler, R.Ph., Director of the Office of Generic Drugs Center

for Drug Evaluation and Research ("CDER") at the FDA, noted that of 42 citizens petitions raising issues about the approvability of generic products, "very few...have presented data or analysis that significantly altered FDA's policies." Of these 42, only three petitions led to a change in FDA policy on the basis of data or information submitted in the petition.

71. Until September 2007, it was the practice of the FDA, well known in the pharmaceutical industry, to withhold ANDA approval until after its consideration of and response to a citizen petition was complete. On this subject, Director Buehler acknowledged that "[i]t is very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions."

X. FACTUAL BACKGROUND

A. Wellbutrin XL

72. Wellbutrin XL is an antidepressant medication. The active ingredient, bupropion HCl, affects chemicals in the brain called neurotransmitters that are used by nerves to transmit messages. When nerves transmit messages, they recycle released neurotransmitters in a process referred to as reuptake. Bupropion HCl works by inhibiting the reuptake of such neurotransmitters as dopamine, serotonin, and norepinephrine. This action results in more dopamine, serotonin, and norepinephrine being available to transmit messages to other nerves, mitigating a neurotransmitter imbalance that some experts believe causes depression.

73. Bupropion HCl is unique and unlike other antidepressants in that its major effect is on dopamine, an effect that is not shared by the selective serotonin reuptake inhibitors such as paroxetine (Paxil), fluoxetine (Prozac), sertraline (Zoloft), or the tricyclic antidepressants for example, amitriptyline (Elavil), imipramine (Tofranil), desipramine (Norpramin). It is chemically

unrelated to selective serotonin reuptake inhibitors or tricyclic antidepressants, or other known antidepressant agents.

74. Bupropion HCl was first synthesized by Burroughs Research in 1966, patented by Burroughs-Wellcome, the predecessor to GSK, in 1974, and approved by the FDA in 1985.

75. Wellbutrin XL is an extended release formulation of bupropion HCl. Extended release technology allows for the continuous and slow release of a drug into the patient's bloodstream over a period of time. A principal advantage of the extended release form of administration is that it increases patient compliance. Symptoms of depression include fatigue and loss of concentration - so that patients with depression may forget or neglect to take their prescribed medication. In the case of bupropion HCl, the better patient compliance achieved with an extended release dosage (as compared to multiple daily doses of an immediate release product) may help overcome one of the important problems encountered by doctors in the treatment of patients with depression.

76. Wellbutrin XL is sold in 150 mg and 300 mg tablets. The usual target dose is 300 mg given once daily - initiated at 150 mg/day and then increased to 300 mg/day as early as day four, if adequately tolerated. The maximum total daily dose of Wellbutrin XL is 450 mg.

77. Wellbutrin XL is identified in the pharmaceutical industry as a "blockbuster" drug. According to IMS data, for the 12 months ended September 2006, Wellbutrin XL 150 mg tablets had U.S. sales of approximately $800 million, and the 300 mg tablets had U.S. sales of approximately $972 million, yielding a total annual U.S. market for Wellbutrin XL of $1.8 billion. Wellbutrin XL is sold throughout the United States, and was ranked in the pharmaceutical industry publication *Drug Topics'* Top 200 Brand Name Drugs by Dollars in 2006 at number 16.

78. According to a pharmaceutical industry study reported in the *Wall Street Journal* on February 21, 2008, from 2005 to 2007, GSK raised the price of Wellbutrin XL by 44.5%.

B. Defendants Acted in Concert with Respect to the Development, Approval, Manufacture, Promotion, and Distribution of Wellbutrin XL, and with Respect to Their Unlawful Efforts to Foreclose Generic Competition

79. On October 26, 2001, Defendants Biovail and GSK entered into an agreement to develop, approve, manufacture, promote, and distribute Wellbutrin XL. At the time, Biovail had access to two formulation patents purporting to cover Wellbutrin XL, U.S. Patent No. 6,096,341 ("the '341 patent"), issued August 1, 2000, and U.S. Patent No. 6,143,327 ("the '327 patent"), a continuation of the '341 patent, issued on November 7, 2000. The patents had an expiration date of 2018.

80. The principal terms of the agreement were between Biovail and GSK were as follows:

(a) Concerning product development and regulatory approval, GSK and Biovail agreed to collaborate in the scientific development and regulatory approval of Wellbutrin XL.

(b) Concerning product manufacture, GSK committed to assist Biovail in qualifying a Biovail facility for manufacture of Wellbutrin XL, and Biovail was responsible for product manufacture.

(c) Concerning promotion, GSK and Biovail were to co-promote Wellbutrin XL in the United States until GSK obtained approval from the FDA. Biovail retained the right to promote Wellbutrin XL in Canada. GSK in fact obtained the assistance of Biovail in promoting Wellbutrin XL in the United States.

(d) Concerning sharing of costs and revenue, GSK agreed to pay Biovail royalties for its development and manufacturing costs based on United States sales of Wellbutrin XL. Biovail agreed to pay royalties to GSK based on Biovail's promotion and sale of Wellbutrin XL in Canada.

81. In August of 2002, GSK filed an NDA seeking approval to market Wellbutrin XL. GSK listed the '341 and '327 patents in the Orange Book as covering Wellbutrin XL.

82. On August 28, 2003, NDA No. 21-515 covering formulations of Wellbutrin XL was issued to GSK and GSK began to market Wellbutrin XL. Pursuant to the agreement between the Defendants, Biovail served as the exclusive manufacturer of Wellbutrin XL.

83. On December 31, 2004, the '341 and '327 patents were formally assigned to Biovail. Biovail continues to be the exclusive manufacturer and supplier of Wellbutrin XL to GSK. In return, pursuant to the agreement between the Defendants, GSK pays Biovail royalties based on GSK's net sales of Wellbutrin XL.

84. By virtue of the co-promotion agreement between GSK and Biovail with respect to Wellbutrin XL, Defendants had a common interest in the development, approval, manufacture, promotion, and distribution of Wellbutrin XL.

85. Further, in all material matters alleged herein, Defendants collaborated and conspired in concerted anticompetitive conduct to exclude generic bupropion HCl extended release from entering the market.

86. As a consequence of this concerted conduct, all Defendants were participants in, responsible for, and benefitted from the anticompetitive conduct alleged herein which had the purpose and effect of injuring competition by unlawfully delaying the entry of generic bupropion HCl extended release products into the market and yielding monopoly profits to Defendants.

C. ANDA Filings by Generic Competitors and Defendants' Sham Litigation Attacks

87. Four generic pharmaceutical product manufacturers sought to enter the bupropion HCl extended release market with inexpensive AB-rated bioequivalent generic formulations in 150 mg and 300 mg dosages. In each case, Defendants individually or in concert commenced sham infringement actions against them. The sham infringement actions were objectively baseless in that no reasonable litigant could realistically expect success on the merits. The actions were filed for the improper purpose of preventing entry of the competing generic products into the market.

1. Anchen

88. On September 21, 2004, Anchen filed an ANDA seeking FDA approval to market generic bupropion HCl extended release in 150 mg and 300 mg formulations. Anchen's ANDA included a Paragraph IV certification that its products would not infringe the '341 or '327 patents.

89. In November 2004, pursuant to Hatch-Waxman, Anchen notified Defendants of its ANDA and Paragraph IV certification.

90. On December 21, 2004, Defendants GSK and Biovail filed an action in the United States District Court for the Central District of California against Anchen alleging infringement of the '341 and '327 patents.

91. On November 14, 2005, the FDA granted tentative approval to Anchen's ANDA for 150 mg and 300 mg bupropion HCl extended release. Anchen was the first generic manufacturer to file an ANDA for 150 mg and 300 mg bupropion HCl extended release. But for Defendants' baseless infringement lawsuit, generic bupropion HCl extended release would have been available to the market on November 14, 2005.

2. Abrika

92. On September 23, 2004, Abrika submitted ANDA 77-285 seeking FDA approval to market a generic 150 mg formulation of bupropion HCl extended release. On October 1, 2004, Abrika amended its ANDA to include a 300 mg generic product.

93. In November 2004, pursuant to Hatch-Waxman, Abrika notified Defendants of its ANDA and its Paragraph IV certification.

94. On December 21, 2004, Defendants GSK and Biovail filed an action in the United States District Court for the Southern District of Florida against Abrika alleging infringement of the '341 and '327 patents.

3. Impax

95. On November 30, 2004, Impax filed ANDA 77-415 seeking FDA approval to market hydrochloride extended release generic bupropion in 150 and 300 mg formulations.

96. On January 20, 2005, pursuant to Hatch-Waxman, Impax notified Defendants of its ANDA and its Paragraph IV certification.

97. On March 7, 2005, Biovail filed an action in the United States District Court for the Eastern District of Pennsylvania against Impax alleging that ANDA 77-415 infringed the '341 patent.

98. On December 15, 2006, the FDA granted Impax tentative approval for its 150 mg bupropion HCl extended release and final approval of its 300 mg product.

4. Watson

99. On July 21, 2005, pursuant to Hatch-Waxman, Watson notified Defendants of its ANDA 77-715 seeking pre-patent expiration approval to market a generic version of Wellbutrin XL in a 300 mg formulation and its Paragraph IV certification.

100. On September 6, 2005, Biovail filed an action in the United States District Court for the Southern District of New York against Watson alleging that Watson's ANDA infringed the '341 patent.

101. On June 13, 2007, the FDA granted Watson final approval for its 300 mg bupropion HCl extended release product.

D. The Generic Formulations Did Not Infringe the '341 Patent and the Cases Filed by Defendants Alleging Infringement Were Shams

1. The Search for a Bupropion HCl Extended Release Formulation that was Free of Stabilizer Had Gone on for Many Years

102. Bupropion HCl, the active ingredient in Wellbutrin XL, has been known for many years to work as an antidepressant. Although there are a variety of bupropion HCl products protected by various formulation patents on the market, the bupropion HCl composition has been off-patent for a very long time.

103. In bulk and in most simple blends, bupropion HCl is stable, i.e., it does not suffer undue degradation over time. In complex mixtures such as granulations or tablets, however, the composition is highly hygroscopic and susceptible to decomposition in water, including atmospheric moisture, *i.e.*, unstable. Because of bupropion HCl's instability, a mechanism is required to improve stability in order to maintain product shelf-life.

104. For many years, researchers working in the field of pharmaceutical product formulation had tried a number of different approaches to improve the storage stability of bupropion HCl. The United States Patent and Trademark Office is filled with bupropion HCl formulation patents that variously disclose the use of organic acids, carboxylic acids, dicarboxylic acids, inorganic acids, acid salts of an amino acids, sodium metabisulfite, and sodium bisulfate as stabilizers for bupropion HCl compositions.

105. GSK's predecessor bupropion HCl formulations use an acidic compound as a stabilizer. According to a GSK memo dated 1983, "[t]he use of hydrochloric acid as a stabilizer for Bupropion Hydrochloride is well documented, and it is used in the current Wellbutrin tablet formulation." The memo explains that the use of hydrochloric acid "dramatically improve[s] product stability."

106. The use for acidic stabilizers in previous bupropion HCl iterations is further documented in U.S. Patent 5,427,798 (the "'798 patent"), one of the principal formulation patents protecting GSK's exclusivity rights in an earlier Wellbutrin iteration, which claims use of the acidic compound as a stabilizer.

107. There are, however, several drawbacks to using acidic stabilizers in pharmaceutical formulations. As a general matter, it is undesirable to add ingredients, such as acids, to a formulation. In addition, using acidic materials in pharmaceutical formulations can require costly production procedures and special equipment. Moreover, the use of acidic stabilizers can make the tableting process more time-consuming and expensive, and require special procedures to address safety and environmental issues.

108. In or about 1999, Biovail began collaborating with pharmaceutical technology company Pharma Pass, LLC ("Pharma Pass") to develop bupropion HCl extended release that was free of stabilizer. Located in Irvine, CA, Pharma Pass had expertise as a developer of advanced oral controlled release technologies and formulations that have been licensed to pharmaceutical companies in the United States and Europe. Pharma Pass was headed by its principal owner, Dr. Pawan Seth, who was a prolific developer of controlled release technologies.

109. The collaboration resulted in the issuance of the '341 patent to Pharma Pass. The

'341 patent described a new formulation of bupropion HCl that eliminated the need for stabilizers. The '341 patent represented a breakthrough in bupropion HCl formulation. Indeed, both Claim 1 and Claim 30 of the '341 patent–the only claims in that patent pursued by Biovail/GSK against the generic manufacturers–expressly described the patented formulation as **"free of stabilizer"** (emphasis added). In the field of pharmaceutical product formulation, this was a substantial achievement.

110. As recognized in the section of the '341 patent entitled, "Background of the Invention," the use stabilizers was critical in the prior art:

> U.S. Pat. No. 5,358,970 and U.S. Pat. No. 5,427,798 both to Burroughs Wellcome [predecessor to Defendant GSK], describe a sustained release formulation of bupropion hydrochloride based on a matrix technology... As bupropion hydrochloride is unstable, the product described in the above patents **requires a stabilizer to achieve stability.** This stabilizer is an acidic compound, preferably cysteine hydrochloride.

(Emphasis added).

111. The complete absence of stabilizer in Defendants' bupropion HCl extended release formulation, including stabilizers composed of acid, was a cornerstone of the invention and is what distinguished it from the prior art. As reflected in the '341 patent section entitled "Summary of the Invention," which is used to inform the public of the claimed invention:

> The invention thus provides **a new bupropion hydrochloride controlled release composition** under the form of a tablet **free of stabilizer of any kind** including those with acidic pH or antioxidant properties.

(Emphasis added).

112. To further underscore the importance of the absence of stabilizer in the bupropion HCl extended release and the novelty of the invention, the '341 patent section entitled, "Detailed Description of the Invention," further explains:

> Surprisingly, it was discovered that the formulation did not lead to any degradation of bupropion hydrochloride though **no stabilizer was present** in the formulation. Stability

> studies were conducted in oven, under the storage test conditions described in the US pharmacopoeia 23rd edition page 1961. Under these conditions no significant change in drug potency could be seen.

(Emphasis added).

113. Thus, the absence of stabilizer in the bupropion HCl extended release formulation to be marketed as Wellbutrin XL was the critical distinguishing characteristic of the '341 patent and the validity of the patent hinged on the free of stabilizer claim.

114. In December 2002, Biovail acquired Pharma Pass, and later formally obtained the rights conferred by the '341 and '327 patents for Wellbutrin XL.

2. It was Clear from the Applications, Data, and Samples Available to Defendants that the Generic Substitutes Were Not Free of Stabilizer

115. Given that the validity of the '341 patent rested on Defendants' purported surprising discovery that the claimed formulation of bupropion HCl extended release was "free of stabilizer," Defendants were necessarily attuned to this claim in evaluating the non-infringement claims by generic competitors.

116. The '341 patent repeatedly distinguishes the invention from the prior art by reference to the presence of stabilizer, and the free of stabilizer claim in the '341 patent was a critical difference between the patents supporting the predecessor Wellbutrin SR formulation and Defendants' Wellbutrin XL formulation.

117. The term "free of stabilizer" is a negative limitation which defines the claimed invention by what it is not. As a result, a generic formulation of bupropion HCl extended release can infringe the '341 patent *only if* the formulation *does not* contain stabilizer.

118. The generic competitors' ANDAs, however, expressly stated that the generic formulations contained stabilizer. Anchen's ANDA, for example, repeatedly identifies diluted hydrochloric acid as an ingredient in the proposed generic formulation, and the ANDA

specification describes the final tablet granulation as containing 0.00 to 1.00% hydrochloric acid. Further, although hydrochloric acid is well-known to work as a stabilizer, to avoid any misunderstanding, the ANDA expressly states that the function of hydrochloric acid is to serve as a "stabilizing agent."

119. In addition, all of the generic competitors provided Defendants with access to their ANDAs and sample products to allow Defendants to determine for themselves that the generic formulations were not free of stabilizer.

120. For example, Defendants obtained access to Impax's ANDA 77-415, as well as additional data, before they filed suit, and GSK sought and received permission from its two outside experts to review Impax's ANDA formulation and related data. In addition, Defendants received the alleged composition of the Impax formulation, along with samples of that product, on July 20, 2005, while their action was in its early stages.

121. Similarly, to support the assertions made in its Paragraph IV certification, on December 3, 2004, prior to the commencement of infringement litigation, Abrika offered Defendants access to relevant portions of its ANDA under the condition that, if the facts in Abrika's notice proved to be true, Defendants would not sue for infringement. Defendants refused this offer. Abrika provided its ANDA on May 26, 2005.

122. Defendants brought and maintained the patent infringement actions without analyzing the materials that would have shown them their claims were baseless. For example, neither the complaint nor the amended complaint filed against Impax described how the Impax product might infringe the '341 patent. Instead, the pleadings simply acknowledge that Biovail *reviewed* the Impax's ANDA and "believe[s] that it infringes" the '341 patent "based on information provided."

123. Further, despite having been ordered by the court in the *Impax* litigation to disclose the basis for their infringement claims by October 2005, as of February 2006, Biovail still had not done so.

124. In patent enforcement actions, a plaintiff is required to construe the claims of its own patent and compare the accused device with the construed claims prior to filing an infringement action in order to comply with Fed. R. Civ. P. 11.

125. Defendants brought and maintained infringement actions against the generic competitors despite knowing or having reason to know that the generic competitors' formulations of bupropion HCl extended release did not infringe because they were not free of stabilizer. The actions were therefore objectively baseless.

3. All Courts Ruling on the Claims Rejected Defendants' Allegations that the Generic Products were Free of Stabilizer and Therefore Infringed

126. All courts reviewing Defendants' infringement claims rejected Defendants' strained attempts to show the competing generic products were free of stabilizer. *See Biovail Laboratories, Inc.* v. *Anchen Pharms, Inc.*, C.A. No. SACV 04-1469-JVS (RCx) (Feb. 8, 2006); *Biovail Laboratories International SRL* v. *Impax Laboratories, Inc.* 433 F. Supp. 501 (E.D. Pa. May 23, 2006); and *Biovail International Laboratories SRL* v. *Abrika, LLLP,* Case No. 04-61704-CIV (Aug. 23, 2006). Further, in the only action in which a dispositive motion was decided, the Court granted summary judgment for the generic competitor, ruling that the proposed generic formulation *did not infringe* the '341 patent because it did contain stabilizer. *See Biovail Labs., Inc.* v. *Anchen Pharms., Inc.*, C.A. No, SACV 04-1469-JVS (RCx) (Aug. 1, 2006).

127. The *Anchen* court was first to rule. At the *Markman* hearing, Biovail claimed that the terms "free of" and "stabilizer" required specialized interpretation, but the Court ruled that

"reliance on Webster's dictionary is proper in this case" and that Defendants' "proposed definition of 'stabilizer' is not found anywhere in the '341 patent and actually contradicts the summary of the invention."

128. Following the *Markman* hearing, the *Anchen* court, ruling on summary judgment, "found that based on the original ANDA, Anchen's ANDA is *not* free of stabilizer." As a result, the Court granted summary judgment on infringement in favor of Anchen.

129. The *Impax* court ruled just as decisively. The court dismissed Biovail's complaints that the amount of stabilizer in the generic product was so small as to "not really be acting as a 'stabilizer,'" noting dryly that "[w]hile this argument may be of philosophical interest it does not comport with the ordinary and accustomed meaning of 'free of stabilizer' . . . If the compound did in fact contain a compound used for stabilizing the tablet, but simply not enough of it, one would not call it 'free of stabilizer,' but rather 'lacking sufficient stabilizer.'"

130. The *Abrika* court similarly rejected Biovail's arguments. The court considered the ordinary meaning of the patent language, and concluded that the Defendants' "narrow construction contradicts the express disclosure of the patent that the claimed invention is 'free of stabilizer of any kind.'" The court's analysis was animated by the distinction between the prior art, which contained stabilizers, and novelty of the purported invention reflected in the '341 patent, which does not.

131. In the three individual cases in which patent claim construction hearings were held, before three different United States District Court judges, in three separate United States District Courts, Defendants' infringement claims were roundly and unanimously rejected.

132. The sham infringement actions brought against *Anchen* and *Abrika* were filed by both GSK and Biovail. In addition, in the *Watson* action, GSK was a party to the action as a

counterclaim defendant. In the course of the litigation of these actions, the generic manufacturers learned that the co-promotion agreement between the Defendants did not extend ownership rights under the '341 or '327 to GSK sufficient to give GSK standing to sue for patent infringement. In response to Abrika's motion to dismiss GSK, GSK stated that it should be permitted to remain in the action because "[a]n injunction is as important to SmithKline as it is to Biovail."

133. Subsequently, GSK moved to withdraw as a plaintiff from the *Abrika* action. In seeking leave to withdraw, GSK represented to the Court that it would be "bound by the decision in the *[Abrika]* action," not sue with respect to the patents and the ANDA products at issue in the action, and provide discovery "as if it were a party to this action." GSK also subsequently withdrew from the *Anchen* action.

134. GSK was not a party to the *Impax* infringement action, but is identified in the complaint filed by Biovail as the owner of the NDA for Wellbutrin XL, the exclusive licensee of the '341 patent, the party responsible for the listing of the '341 patent in the Orange Book, and the seller of Wellbutrin XL.

135. GSK made clear by its filing and withdrawal in the *Anchen* and *Abrika* actions that it remained a real party in interest in the infringement actions, would continue to act in concert with respect to matters involving Wellbutrin, the XL sham litigation, and petitioning activities, and would continue to benefit from the anticompetitive conduct alleged herein.

136. GSK's continued interest and involvement in the infringement litigation is underscored by the action took at the close of the *Abrika* litigation. Particularly, at the time Biovail settled the action, GSK filed a motion seeking leave to review all sealed documents within the docket in order to protect all GSK documents from public disclosure. Subsequently GSK requested that all such documents be destroyed. GSK's request shows that its involvement

and interest in the infringement litigation extended beyond the date of its withdrawal from the litigation.

E. The '327 Patent Did Not Cover Wellbutrin XL - Listing It in the Orange Book by Defendants Interfered with the ANDA Approval Process and Impaired Competition and Bringing Suit Based on It Was a Sham

137. The '327 patent is a continuation of the '341 patent. Like the '341 patent, the'327 patent provides for a bupropion HCl extended release tablet, free of stabilizer. Unlike the '341 patent, the '327 patent also provides a second coat consisting of a polymer and a plasticizer which assists in controlling the release.

138. The formulation as described in the '327 patent, however, does not conform to the FDA's requirements for bioequivalence with the parent drug. Particularly, the pharmacokinetic and relative bioavailability data show that the formulation as taught in the '327 patent does not display a bioavailability profile within 80 %-125 % of the bioavailability profiles of the bupropion HCl parent formulations, as is required by FDA bioequivalence regulations.

139. Accordingly, the '327 patent could not reasonably be asserted against a generic manufacturer of Wellbutrin XL and, therefore, should not have been listed in the Orange Book as covering Wellbutrin XL.

140. GSK and Biovail knew or had reason to know that the '327 patent did not cover Wellbutrin XL. Despite that, Defendants caused the '327 patent to be listed in the Orange Book referenced to Wellbutrin XL.

141. Despite their knowing improper listing of the '327 patent in the Orange Book, in lodging their infringement actions against Anchen and Abrika, GSK and Biovail asserted infringement not only of the '341 patent, but also the '327 patent. No reasonable litigant could realistically have expected success on the merits of an infringement action based on the '327

patent because the patent did not cover Wellbutrin XL. Rather, the claim was asserted to defeat generic competition.

142. Subsequent to filing their lawsuits against Anchen and Abrika, Defendants commenced actions against Impax and Watson, but asserted only the '341 patent. In addition, Defendants also subsequently voluntarily withdrew their claims under the '327 patent. Defendants took these actions because they knew they had improperly listed the '327 patent in the Orange Book and commenced litigation based on it, and knew they had been exposed.

F. Defendants' Citizen Petition Did Not Present Legitimate Scientific or Legal Concerns about the Generic Manufacturers' ANDAs, and Was Filed for the Purpose of Further Delaying Generic Entry

143. On December 20, 2005, more than a year after the generic manufacturers filed their ANDAs, and a month after the FDA determined that Anchen's generic bupropion HCl extended release formulation was bioequivalent to Wellbutrin XL and therefore gave tentative approval to Anchen's ANDA, Biovail filed a citizen petition with the FDA. The citizen petition was not based on any information or data that had not been previously available to Defendants.

144. The citizen petition requested that the FDA refuse to approve any bupropion HCl extended release ANDA unless the ANDA included additional studies and data concerning bioequivalence including, in particular, data demonstrating not only that the generic bupropion HCl extended release formulations were bioequivalent to Wellbutrin XL, but also that they were bioequivalent to the parent drugs, Wellbutrin IR and Wellbutrin SR.

145. Under Hatch-Waxman and FDA regulations, an ANDA product need be shown to be bioequivalent only to the Referenced Listed Drug upon which the requested ANDA approval is predicated. In fact, Hatch-Waxman specifically forbids the FDA from requiring an ANDA to contain bioequivalence information from other than the referenced drug.

146. Many branded extended release drugs that were approved as part of a line extension from immediate release versions of the drug were approved based on bioequivalence studies as between the branded extended release and branded immediate release products. The FDA has never deemed it necessary or appropriate to require ANDA applicants to conduct their own bioequivalence studies comparing a generic extended release drug to the branded immediate release product.

147. Prior to approving brand-name Wellbutrin XL, the FDA required GSK to prove that Wellbutrin XL was bioequivalent to Wellbutrin IR and Wellbutrin SR. In addition, prior to approving the bupropion HCl extended release ANDAs, the FDA required the generic manufacturers to prove that their products were bioequivalent to Wellbutrin XL.

148. Thus, the demands for additional bioequivalence studies and data set forth in the citizen petition were contrary to Hatch-Waxman's mechanisms to avoid time-consuming and redundant studies, and contrary to FDA protocols, and were therefore without basis in law or practice. Moreover, the studies supporting the generic manufacturers' ANDAs were sufficient to demonstrate the bioequivalence Biovail purported to demand. Thus, there was no scientific or legal basis to require studies showing bioequivalence between the generic bupropion HCl extended release applicants and the Wellbutrin parent drugs.

149. The citizen petition also demanded additional studies to measure three metabolites in the ANDA applicants' products. Biovail, however, offered no competent support for imposing this broad additional bioequivalence requirement. Moreover, FDA regulations and guidance, as set forth in the FDA's governing guidance to the industry, *Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations* (March 2003), make clear that such additional requirements are in large part unnecessary. Thus, the demand for

metabolite studies was overbroad and fundamentally baseless.

150. The citizen petition was objectively baseless, relying on unsubstantiated theories lacking scientific support and misapplication of governing legal and regulatory standards. It was nothing more than a last minute attempt to extend Defendants' monopoly on an overpriced brand name drug by slowing market entry of bioequivalent and more affordable generic products through the abuse of governmental processes. In short, it was a sham.

151. On December 14, 2006, the FDA responded in relevant part denying the citizen petition. The FDA condemned Biovail's conduct, stating that Defendants did not have "the right to be free of generic competition" once their patents had been held to be unenforceable, and that under these circumstances, "Biovail [should] not be permitted to shield its market share." The FDA ruled that the generic manufacturers' bupropion HCl extended release products and Wellbutrin XL "would be expected to have the same clinical effect and safety profile when administered under the conditions for use prescribed, recommended, or suggested in the labeling. *You have not submitted any data or information to suggest otherwise"* (emphasis added).

152. In addition, notwithstanding it acquiescence to Biovail's request for measurements of the hydroxybupropion metabolite, the FDA disparaged the Biovail submission, noting, "*You did not submit any evidence* in the Petition to support the conclusion that [the other metabolites] contribute meaningfully to safety and/or efficacy of Wellbutrin XL" (emphasis added). The FDA similarly criticized Biovail for failing to submit data to substantiate its claim on other complaints.

153. On December 14, 2006, the same day it denied the citizen petition, the FDA granted final approval Anchen's and Abrika's ANDAs.

154. Biovail's filing of the sham citizen petition had the intended effect of delaying

market entry of generic bupropion HCl extended release. Defendants were aware of the FDA's practice of withholding ANDA approval until after its consideration of and response to a citizen petition was complete. Had Biovail not filed the sham citizen petition, Anchen, the first generic manufacturer to file an ANDA for bupropion HCl extended release, would have received final approval of its 150 mg and 300 mg formulations on August 25, 2006, the date upon which the *Anchen* court entered judgment in the sham infringement litigation. Instead, it was not until December 14, 2006, *four months later,* when Anchen's ANDA received final approval.

155. In response to the FDA's denial of the citizen petition and concurrent approval of Anchen's application to market its generic substitute, on December 18, 2006, Biovail filed a motion in an action previously brought *against the FDA* seeking an order to enjoin the effectiveness of the FDA's approval of Anchen's application thereby preventing the launch of generic versions of Wellbutrin XL. Denying the motion, the court ruled that "the public also has a well-recognized interest in 'receiving generic competition to brand name drugs as soon as is possible,' and a 'delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices.'" *Biovail Corp et al. v. U.S. Food and Drug Administration,* C.A. 14-0687 (RMU) (March 22, 2007).

G. Biovail Entered into Settlements with the Generic Manufacturers that Further Prevented Generic Substitutes from Reaching the Market

156. Following the FDA's denial of the citizen petition and approval on December 14, 2006 of Anchen's ANDA for the 150 mg and 300 mg bupropion HCl extended release product, Anchen transferred its 180-day exclusivity period for the 300 mg product in favor of Impax, who, in partnership with Teva Pharmaceuticals, another generic manufacturer, launched its own generic bupropion HCl extended release 300 mg product.

157. On March 5, 2007, Biovail announced the settlement of the infringement actions

against Anchen, Impax, and Watson. Under the settlement agreement, Biovail granted Anchen/Impax/Teva an exclusive license to market a generic 300 mg bupropion HCl extended release product during Anchen's 180-day exclusive marketing period, from December 13, 2006 until June 13, 2007, with Watson coming on market thereafter. On July 31, 2007, following settlement negotiations, Defendants also settled their action against Abrika.

158. The aforementioned settlement agreements (hereinafter the "Settlement Agreements") constitute contracts, combinations and/or conspiracies, and constitute a conscious commitment to a common scheme, designed to achieve an unlawful objective, between Defendants on the one hand, and Anchen, Impax, Watson, and Abrika on the other.

159. Biovail entered the Settlement Agreements even though only one of the actions had gone to summary judgment and the purported patents *did not expire until 2018,* thus underscoring the sham nature of the litigation that had delayed generic entry.

160. At the time, Impax's motion for summary judgment based on non-infringement was pending against Biovail.

161. While the Settlement Agreements permitted generic competition on the 300 mg bupropion HCl extended release product, they barred the generic competitors from releasing their 150 mg bupropion HCl extended release formulations until 2008. In addition, even after the agreements permitted Anchen/Impax/Teva to launch a 150 mg formulation of bupropion HCl extended release, they barred Watson from doing so until six months later. As a result, through the settlement of the generic infringement litigation, Biovail continued to foreclose generic competition, resulting in overcharges in the market for Wellbutrin XL and its AB-rated generic equivalents to purchasers.

XI. CLASS ACTION ALLEGATIONS

162. Plaintiffs bring this action under Rule 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of themselves and the following class:

> All persons and entities in the United States who purchased Wellbutrin XL directly from one or more of the Defendants at any time from November 14, 2005 through the present and continuing until the effects of Defendants' anticompetitive conduct cease (the "Class Period"). Excluded from the class are Defendants and their parents, employees, subsidiaries, and affiliates, and federal governmental entities (the "Class").

163. The Class is so numerous that joinder of all members is impracticable. Plaintiffs believe that the Class numbers one hundred or more.

164. There are numerous questions of law and/or fact common to the Class, including:

a. whether Defendants willfully obtained and/or maintained monopoly power over Wellbutrin XL and its generic equivalents;

b. whether Defendants improperly listed the '327 patent in the Orange Book;

c. whether Defendants' multiple actions asserting infringement of the '341 and '327 patents and seeking additional FDA review were baseless;

d. whether Defendants engaged in sham litigation to prevent competition;

e. whether Defendants filed their citizen petition to prevent competition;

f. whether Defendants unlawfully excluded competitors and potential competitors from the market for Wellbutrin XL and its AB-rated generic bioequivalents; and

g. whether the Patent Litigation was objectively baseless;

h. whether Defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States;

i. whether Defendants maintained monopoly power by delaying generic entry;

j. whether the law requires definition of a relevant market when direct proof of monopoly power is available, and if so the definition of the relevant

market;

k. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

l. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and

m. the quantum of aggregate overcharge damages to the Class.

165. These and other questions of law and fact are common to the members of Class and predominate over any questions affecting only individual members.

166. Plaintiffs' claims are typical of the claims of the Class because all Class members paid overcharges, and thus suffered antitrust injury, as a result of Defendants' wrongdoing, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

167. Plaintiffs will fairly and adequately represent, and protect the interests of, the Class. Plaintiffs have retained counsel experienced in class action and pharmaceutical antitrust litigation, and Plaintiffs have no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

168. A class action is superior to any other available methods for the fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty that will be encountered in the management of the claims advanced by the Class that would preclude class certification.

XII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Monopolization Under Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2

169. Plaintiffs incorporate by reference the preceding allegations.

170. Defendants knowingly and intentionally engaged in an anticompetitive scheme

designed to block and delay entry of AB-rated generic versions of Wellbutrin XL and willfully to maintain their monopoly power. This scheme included

a. filing objectively and subjectively baseless patent infringement litigation regarding the '341 and '327 Patents against would-be sellers of generic Wellbutrin XL;

b. listing the '327 Patent in the Orange Book;

c. filing an objectively and subjectively baseless Citizen Petition with the FDA; and

d. entering into the Settlement Agreements

171. By their scheme, Defendants intentionally and wrongfully maintained their monopoly power with respect to Wellbutrin XL in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for their extended-release bupropion hydrochloride requirements.

172. Plaintiffs and members of the Class have been injured in their business or property by Defendants' antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their extended-release bupropion hydrochloride requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent, flows from that which makes Defendants' conduct unlawful, and Plaintiffs and the Class are the proper entities to bring a case concerning this conduct.

SECOND CLAIM FOR RELIEF

Conspiracy to Monopolize between GSK and Biovail Under Section 2 of the Sherman Act, 15 U.S.C. § 2

173. Plaintiffs incorporate by reference the preceding allegations.

174. With respect to all of the conduct complained of above, at all relevant times the

GSK defendants acted in concert with the Biovail defendants to maintain their monopoly power.

175. Specifically, GSK and Biovail affirmatively, knowingly, and intentionally acted in concert to: (a) wrongfully list the '327 patent in the Orange Book; (b) wrongfully conduct baseless infringement litigation on the '341 and '327 patents solely to trigger the automatic 30-month stay prohibiting the FDA from granting final approval permitting the ANDA filers to market their less-expensive generic bupropion HCl extended release; (c) wrongfully file a citizen petition with the FDA in an attempt to delay generic versions of Wellbutrin XL from entering the market; and (d) wrongfully enter into agreements with generic competitors to forestall generic competition.

176. The acts done by each of the Defendants as part of, and in furtherance of, their contract, combination or conspiracy were authorized, ordered, or done by their officers, agents, employees or representatives while actively engaged in the management of Defendants' affairs.

177. The purpose and effect of Defendants' scheme was to exclude generic competition from the bupropion HCl extended release market in order to maintain market power in the market for Wellbutrin XL and its AB-rated generic equivalents, charge supracompetitive prices, and reap monopoly profits.

178. GSK and Biovail specifically intended to maintain monopoly power in the relevant market, and injured Plaintiffs and the other members of the Direct Purchaser Class thereby.

179. GSK and Biovail each committed at least one overt act in furtherance of the conspiracy. By their scheme, Defendants intentionally and wrongfully maintained their monopoly power with respect to Wellbutrin XL in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class

paid artificially inflated prices for their extended-release bupropion hydrochloride requirements.

180. Plaintiffs and members of the Class have been injured in their business or property by Defendants' antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their extended-release bupropion hydrochloride requirements than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type antitrust laws were designed to prevent, flows from that which makes Defendants' conduct unlawful, and Plaintiffs and the Class are the proper entities to bring a case concerning this conduct.

THIRD CLAIM FOR RELIEF

Violation of Section 1 of the Sherman Act, 15 U.S.C. § 1

181. Plaintiffs incorporate by reference the preceding allegations.

182. The Settlement Agreements, and each of them, constitute contracts, combinations and conspiracies that substantially, unreasonably, and unduly restrain trade in the relevant market(s), and harmed Plaintiffs thereby.

183. The Agreements cover a sufficiently substantial percentage of the relevant market(s) to harm competition.

184. Each Defendant is *per se* liable for the creation, maintenance, and enforcement of the Settlement Agreements, and each of them.

185. Alternatively, each Defendant is liable for the creation, maintenance, and enforcement of the Settlement Agreements under a "quick look" and/or rule of reason standard.

186. There is no legitimate, procompetitive business justification for the Settlement Agreements, or any of them, that outweighs their harmful effect. Even if there were some conceivable such justification, the Settlement Agreements are broader than necessary to achieve

such a purpose.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following:

A. Judgment in its favor and against Defendants, jointly and/or severally, for damages representing the overcharges paid by Plaintiffs and the other members of the Class, trebled;

B. Pre- and post-judgment interest; and

C. Costs of suit, including reasonable attorneys' fees.

XIV. JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs demand a trial by jury of all of the claims asserted in this Complaint so triable.

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